

Practitioner's Docket No.

1062/D45

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

Inventor(s)

for

Title of invention

the specification of which is being transmitted herewith

OR

In re application of:

Application No.: 10/671,278

Group No.: Not Assigned

Filed: September 25, 2003

Examiner: Not Assigned

For: System and Method for Aerosol Delivery

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

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Mailing Label No. _____ (mandatory)

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☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Samuel J. Petuchowski, Esq.

(type or print name of person certifying)

Date: January 29, 2004

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"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e. requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

INFORMATION DISCLOSURE STATEMENT

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

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NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

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WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ JEPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

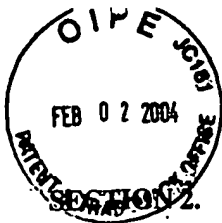
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FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

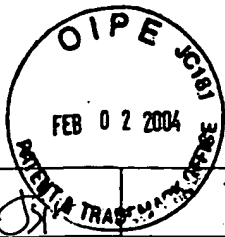
Applicants: Attorney Docket: 1062/D45
 Serial No: 10,671,278 Art Group Unit: Not Assigned
 Date Filed: September 25, 2003 Examiner Name: Not Assigned
 Invention: System and Method for Aerosol Delivery

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
JSH	AA	US 4,370,968	Feb. 1, 1983	Gebhart, et al.	128/716
JSH	AB	US 4,484,577	Nov. 27, 1984	Sackner, et al.	128/203.28
JSH	AC	US 5,349,852	Sept. 27, 1994	Kamen, et al.	73/149
JSH	AD	US 5,526,844	June 18, 1996	Kamen, et al.	137/614.11
JSH	AE	US 5,533,389	July 9, 1996	Kamen, et al.	73/149
JSH	AF	US 5,575,310	Nov. 19, 1996	Kamen, et al.	137/614.11
JSH	AG	US 5,842,468	Dec. 1, 1998	Denyer, et al.	128/200.23
JSH	AH	US 5,884,620	Mar. 23, 1999	Gonda, et al.	128/200.14
JSH	AI	US 5,906,202	May 25, 1999	Schuster, et al.	128/203.23
JSH	AJ	US 5,957,124	Sept. 28, 1999	Lloyd, et al.	128/200.22
JSH	AK	US 6,008,468	Dec. 28, 1999	Tanaka, et al.	219/121.71
JSH	AL	US 6,026,808	Feb. 22, 2000	Armer, et al.	128/200.23
JSH	AM	US 6,095,141	Aug. 1, 2000	Armer, et al.	128/204.26
JSH	AN	US 6,167,880 B1	Jan. 2, 2001	Gonda, et al.	128/200.14
JSH	AO	US 6,192,882 B2	Feb. 27, 2001	Gonda	128/203.21
JSH	AP	US 6,349,719 B2	Feb. 26, 2002	Gonda	128/200.14
JSH	AQ	US 2002/0153006	Oct. 24, 2002	Zimlich, Jr., et al.	128/200.14

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JSH	AR	WO	98/48873	Nov. 5, 1998	Gonda, et al.	A61M 11/00
JSH	AS	WO	99/37347	July 29, 1999	Gonda	A61M 11/00
JSH	AT	WO	01/58514 A1	Aug. 16, 2001	Crockford	A61M 15/00

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
JSH	AU	Inamed GmbH	"RAP - Today's Most Sensitive System for Monitoring Lung Emphysema," <i>Respiratory Aerosol Probe</i> : 1/19/2004,



	http://www.inamed.de/EN/main/02_produkte/05_rap.htm ; pgs. 1-2.
--	---

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to 37 CFR 1.98 9(a)(2)(i) and 37 CFR 1.491(b), in which the USPTO waived the requirement for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 37,910

Tel. No.: (617) 443-9292

Customer No.: 002101

01062/00D45 292678.1



SIGNATURE OF PRACTITIONER

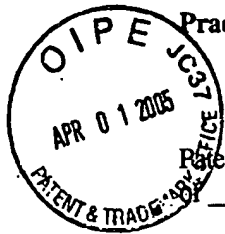
Samuel J. Petuchowski, Esq.

(type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110



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Group No.: N/A

Filed: September 25, 2003

Examiner: N/A

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Commissioner for Patents

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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37 C.F.R. SECTION 1.8(a)

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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.



Signature

Samuel J. Petuchowski

Date: March 30, 2005

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4/11/05

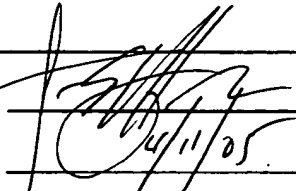
SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gray et al. Attorney Docket: 1062/D45
 Serial No: 10/671,278 Art Group Unit: N/A
 Date Filed: September 25, 2003 Examiner Name: N/A
 Invention: System and Method for Aerosol Delivery

**LIST OF PATENTS AND PUBLICATIONS FOR
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U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
TJA	BD	US 4,811,595 A	March 14, 1989	Poole et al.	
TJA	BE	US 5,349,852 A	Sept. 27, 1994	Finn et al.	

Examiner Signature:	
Date Considered:	4/11/05
<p>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation <i>if not</i> in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent
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(type name of inventor who is signing)

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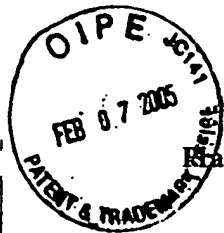


SIGNATURE OF PRACTITIONER

Samuel J. Petuchowski

Bromberg & Sunstein LLP
125 Summer Street, 11th Floor
Boston, MA 02110

01062/00D45 374474.1



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(Supplemental Information Disclosure Statement--page 1 of 7)

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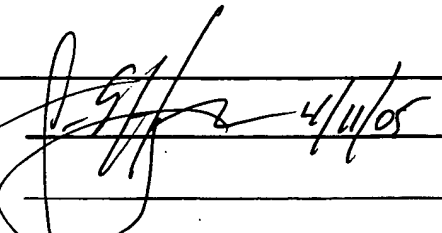
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JSH	AX	US 5,641,892	June 24, 1997	Larkins et al.	73/19.03
JSH	AY	US 6,119,684	Sep. 19, 2000	Nöhl et al.	128/200

Examiner Signature: 

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Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

**Section 7B. Concise Explanation of Non-English Language Listed Information Items—English
Language Version of EPO Search Report**

[Replace with EPO Search Report]

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 37,910

Tel. No.: (617) 443-9292

Customer No.: 002101

01062/00D45 360672.1



SIGNATURE OF PRACTITIONER

Samuel J. Petuchowski

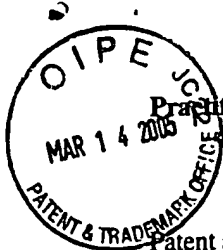
(type or print name of practitioner)

Bromberg & Sunstein LLP

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110



Practitioner's Docket No. 1062/D45

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application
of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Gray et al.

Application No.: 10/671,278

Group No.: N/A

Filed: September 25, 2003

Examiner: N/A

For: System and Method for Aerosol Delivery

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Supplemental Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

[x] deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

[x] with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Samuel J. Petuchowski

Date: March 10, 2005

*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☒ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

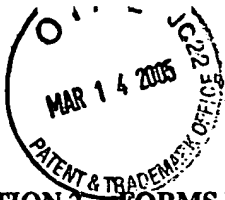
NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gray et al. Attorney Docket: 1062/D45
Serial No: 10/671,278 Art Group Unit: N/A
Date Filed: September 25, 2003 Examiner Name: N/A
Invention: System and Method for Aerosol Delivery

LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
JSH	AZ	US 5,156,776	Oct. 20, 1992	Loedding et al.	261/27

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
JSH	BA	Gebhart et al.	"A New Device for Aerosol and Gas Inhalation Studies and Its Application in Lung Investigations", <i>Journal of Aerosol Science</i> , Vol. 11, No. 3, pages 237-238, 1980.
JSH	BB	Gebhart et al.	"Individual Aerosol Exposure Unit for Small Rodents Using Photometry", <i>Journal of Aerosol Science</i> , Vol. 19, No. 7, pages 1105-1108, 1988.
JSH	BC	Heyder et al.	"Experimental Studies of the Total Deposition of Aerosol Particles in the Human Respiratory Tract", <i>Journal of Aerosol Science</i> , Vol. 4, pages 191-208, 1973.

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included..."

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SIGNATURE OF INVENTOR

(type name of inventor who is signing)

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SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

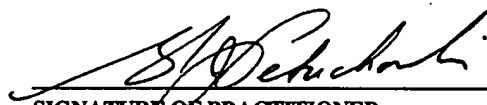
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 37,910

Tel. No.: (617) 443-9292

Customer No.: 002101



SIGNATURE OF PRACTITIONER

Samuel J. Petuchowski

Bromberg & Sunstein LLP
125 Summer Street, 11th Floor
Boston, MA 02110

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